REMARKS

In response to the Office Action mailed June 9, 2003, submitted herewith is a Petition for Extension of Time from September 9, 2003 to December 9, 2003. This Petition includes an authorization to charge the required fee.

In view of the above amendments and the following remarks, reconsideration and allowance of this application are requested. Claims 1-17 are pending with claims 1-3 and 15 being independent. Claims 1, 3, 4, and 7-10 have been amended and claims 14-17 have been added. Because support for these amendments and new claims is found in the application as filed, no new matter has been added. For example, claim 1 has been amended to recite that the fexofenadine hydrochloride is in the solid state. Support for this amendment is found at least in the specification as filed at page 3, lines 9-15 (which discloses recovering the fexofenadine hydrochloride from the solvent); and page 3 line 20 through page 4, line 7 (which discloses taking a wet mixture of fexofenadine hydrochloride and solvent, and recovering the fexofenadine hydrochloride from the solvent in a process that involves two different drying steps). Claims 2, 3, and 7-10 have been amended merely to put these claims in better condition for examination.

New claim 15 recites the fexofenadine hydrochloride being in a solid state. Support for this claim is found in the specification at least at page 3, lines 9-15; and page 3 line 20 through page 4, line 7. New claims 14 and 16 recite the fexofenadine hydrochloride being synthetic. Support for these claims is found in the specification at least at Example 1 at pages 5 and 6. Similarly, the other examples also support this amendment. Support for new method claims 15-17 find support in the specification in the Examples and at page 3, lines 9-15; page 3, line 20 through page 4, line 7; and page 1, line 24 through page 2, line 23.

Further, as requested by the Examiner, an amended abstract is submitted.

Claim 1 is directed to a solid fexofenadine hydrochloride in an amorphous form.

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by Coutant (Journal of Chromatography), and obvious over Meiwes (U.S. Patent No. 5,990,127) in view of Berge (Journal of Pharmaceutical Sciences). Claims 1-13 also have been rejected under as being obvious over either of Carr (U.S. Patent No. 4,254,129), Carr (U.S. Patent No. 4,285,957), Henton (WO 95/31437), or Woosley (U.S. Patent No. 5,375,693) in view of Lieberman, Suzuki, Corrigan, Nuemberg, and Sato. Claim 1 also has been provisionally rejected under 35 U.S.C. 102(e),(f) or (g) as being anticipated by US2002/01776608 or alternatively claims 1-13 are provisionally rejected under 35 U.S.C. 103(a) and under 35 U.S.C. 102(f) or (g) as being anticipated by WO02/066429.

I. Rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Coutant

Coutant discloses administering terfenadine and then detecting and quantifying the acid metabolite of terfenadine (i.e., fexofenadine) in the plasma. The Office Action asserts that the fexofenadine in the plasma is a liquid and therefore is amorphous. The Office Action further asserts that the fexofenadine in the plasma is in the form of fexofenadine hydrochloride because in its native environment the fexofenadine cyclic amine should in its acid addition form and as chloride is the most abundant anion in the blood, fexofenadine hydrochloride should be present. However, Coutant does not describe or suggest a solid, amorphous form of fexofenadine hydrochloride, as recited in claim 1.

Instead of disclosing a solid, amorphous form of fexofenadine hydrochloride, Coutant discloses fexofenadine hydrochloride in the blood as a liquid as the metabolite of terfenadine. As described in the introduction to the article, after administering the terfenadine, it undergoes metabolism to form the acid metabolite, fexofenadine.

Further, Applicants recognize that Coutant also discloses the use of a solid reference material of the terfenadine acid metabolite. However, Coutant does not describe or suggest whether the reference material is in a crystalline form or an amorphous form. Thus, Coutant cannot be characterized as describing or suggesting that the reference material is the amorphous form of fexofenadine hydrochloride. Moreover, Coutant does not describe or suggest whether the reference material is a salt of fexofenadine, much less the hydrochloride salt of fexofenadine. Accordingly, for at least these reasons claim 1 is allowable over Coutant.

As amended, independent claim 2 is allowable over Coutant for the same reasons that claim 1 is allowable over Coutant. Specifically, claim 2 recites the solid, amorphous form of fexofenadine hydrochloride. Because Coutant describes dissolving the acid metabolite reference material in methanol, it is reasonable to assume that the reference material is in the solid state. Again, however, Coutant does not describe or suggest whether the reference material is in either the crystalline form or the amorphous form. Coutant also does not describe or suggest whether the reference material is a salt of fexofenadine, much less the hydrochloride salt of fexofenadine. Accordingly, claim 2 is allowable over Coutant.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Claim 15 is allowable over Coutant for the same reasons that claims 1 and 2 are allowable over Coutant, namely, (1) Coutant does not describe or suggest a solid, amorphous form of fexofenadine hydrochloride and (2) Coutant does not describe or suggest whether the reference material is a salt of fexofenadine, much less the hydrochloride salt of fexofenadine. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over Coutant.

II. Rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable ver Meiwes in view of Berge

Meiwes discloses a lyophilized product of fexofenadine. See Col. 7, line 55-60, Col. 8, line 19-21. Meiwes also discloses obtaining fexofenadine by incubating phosphorylated derivatives of alpha-(p-tert-butylphenyl)-4-(alpha-hydroxy-alpha-phenylbenzyl)-1-piperindinylbutanol with a fungus of the genus Cunninghamella or Absidia. However, recognizing that Meiwes does not disclose fexofenadine hydrochloride, the Office Action relies on Berge's disclosure of a listing of 67 salts that have been approved by the Food and Drug Administration to assert that it is prima facie obvious to use the hydrochloride acid salt.

However, neither Meiwes nor Berge, taken separately or in combination, describe or suggest solid fexofenadine hydrochloride in an amorphous form. At most, Meiwes describes using a culturing technique to form fexofenadine. Although the Office Action then relies on Berge to supply the hydrochloride salt, Applicants respectfully submit that Berge merely lists FDA approved salts but does not provide any motivation to ignore the 66 other FDA approved salts and select the hydrochloride salt as asserted in the Office Action. In fact, Berge teaches away from making such a selection. Instead, Berge describes the difficulties encountered with respect to selecting a salt:

> "[c]hoosing the appropriate salt can be a very difficult task, since each salt imparts unique properties to the parent compound."
>
> "Salt-forming agents are often chosen empirically. Of the many salts synthesized, the preferred form is selected by pharmaceutical chemists primarily on practical basis: cost of raw materials, ease of crystallization, and percent yield. Other basic considerations include stability, hygroscopicity, and flowability of the resulting bulk drug. Unfortunately, there is no reliable way of predicting the influence of a particular salt species on the behavior of the parent compound. Furthermore, even after many salts of the same basic agent have been prepared, no efficient screening techniques exist to facilitate selection of the salt most likely to exhibit the desired pharmacokinetic, solubility, and formulation profiles."

See Berge, page 1. Berge clearly points out the difficult in selecting one salt from the laundry list of FDA approved salts: each salt imparts unique properties to the parent compound and no efficient screening techniques exist to facilitate selection of the salt most likely to exhibit the desired pharmacokinetic, solubility, and formulation profiles. In pointing out the difficulties in selecting a salt, Berge indicates that more than routine experimentation must be conducted to select a particular salt to use. As such, one of skill in the art would have found no motivation in Berge to select as the salt of choice from amongst the 67 listed salts, the hydrochloride salt. For at least these reasons claim 1 is allowable over Meiwes and Berge, taken separately or in combination.

As amended, independent claim 2 is allowable over Meiwes and Berge for the same reasons that claim 1 is allowable over Meiwes and Berge. Specifically, like claim 1, claim 2 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over Coutant.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over Meiwes and Berge for the same reasons that claims 1 and 2 are allowable over Meiwes and Berge. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over Meiwes and Berge.

III. **Rejection of claims 1-13 under 35 U.S.C. 103(a) as being unpatentable in view of either of the Carr '129 patent, the Carr '957 patent, Henton or Woosley in view of Lieberman, Suzuki, Corrigan, Neurnberg, and Sato CA supplemented with Meiwes.**

Carr et al ('129 and '957 patents) are divisional patents that disclose recrystallized fexofenadine. See Col. 13, Example 3. Fexofenadine also is disclosed in Henton (page 11, lines 22-29) and Woosley (Col. 10, Example 1B). Recognizing that neither the Carr patents, Henton, or Woosley disclose the amorphous form of fexofenadine, the Office Action relies on Lieberman, Suzuki, Corrigan, Nuernberg, and Sato to provide evidence that spray drying and freeze drying processes are size reduction processes for pharmaceutical products and such size reduction enhances drug dissolution. However, none of these references, taken separately or in combination, describe or suggest a solid fexofenadine hydrochloride in an amorphous form.

The Carr '957 and '129 patents and Woosley disclose recrystallizing fexofenadine from a solution to give fexofenadine. Thus, these three patents fail to describe or suggest solid, fexofenadine hydrochloride in an amorphous form. At most, these patents disclose liquid fexofenadine, which the Office Action asserts to be amorphous, and solid fexofenadine. Neither Lieberman, Suzuki, Corrigan, Nuernberg, and Sato cure the deficiencies of the Carr '957 and '129 patents and Woosley. Specifically, Lieberman states that "[t]heoretical considerations predict that amorphous solids will, in general, be better absorbed than will crystalline ones." Lieberman also points to micronization as increasing two fold the bioavailability of drug. Thus, one of skill in the art reading Lieberman would have been motivated to rely on micronization rather than using amorphous solids because Lieberman demonstrated an increase in bioavailability by

micronizing but merely pointed to theoretical considerations indicating benefits from forming the amorphous solid. Thus, Lieberman does not teach using amorphous solids. Moreover, Lieberman does not describe or suggest the hydrochloride salt of fexofenadine. Further, there is no motivation in either the Carr '957 and '129 patents, Woosley, or Lieberman to combine the solid fexofenadine with the amorphous solid of Lieberman because Lieberman teaches micronizing. Finally, for the sake of argument even if there was a motivation to combine the Carr '957 and '129 patents or Woosley with Lieberman, the result would not be the solid, amorphous fexofenadine hydrochloride of claim 1. Instead, at most, the result would be solid, micronized fexofenadine. Accordingly, claim 1 and dependent claim 14 are allowed over the Carr '957 and '129 patents, Woosley, and Lieberman, taken separately or in combination.

As amended, independent claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Lieberman, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Lieberman. Specifically, like claim 1, claim 2 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Lieberman.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over the Carr '957 and '129 patents, Woosley, and Lieberman, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Lieberman. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over the Carr '957 and '129 patents, Woosley, and Lieberman.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over the Carr '957 and '129 patents, Woosley, and Lieberman for the same reasons that claims 1 and 2 are allowable over the Carr '957 and '129 patents, Woosley, and Lieberman. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over the Carr '957 and '129 patents, Woosley, and Lieberman.

Suzuki discloses particle size reduction by freeze drying using a water-potassium chloride system and a water-sodium chloride system. See page 1214. Suzuki further discloses that some antibiotics and enzymes are frequently freeze-dried as amorphous form because the amorphous form is superior to the crystalline form with respect to solubility. However, Suzuki denigrates the use of the amorphous form by stating: "their [amorphous form] hygroscopisity [sic] and reduced stability may be disadvantageous in practical use." See page 1218. Thus, one of skill in the art reading Suzuki would not have been motivated to use the amorphous form. In fact, because of the denigration of the amorphous form, one of skill in the art would have been taught away from using the amorphous form. Thus, contrary to the Office Action, one of skill in the art reading the Carr '957 and '129 patents, Woosley, and Suzuki would not have been motivated to use the solid fexofenadine hydrochloride in an amorphous form, as claimed in claim 1. Accordingly claim 1 and dependent claim 14 are allowable over the Carr '957 and '129 patents, Woosley, and Suzuki, taken separately or in combination.

As amended, independent claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Suzuki, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Suzuki. Specifically, like claim 1, claim 2 recites the solid, amorphous form of fexofenadine

hydrochloride. Accordingly, claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Suzuki.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over the Carr '957 and '129 patents, Woosley, and Suzuki, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Suzuki. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over the Carr '957 and '129 patents, Woosley, and Suzuki.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over the Carr '957 and '129 patents, Woosley, and Suzuki or the same reasons that claims 1 and 2 are allowable over the Carr '957 and '129 patents, Woosley, and Suzuki. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over the Carr '957 and '129 patents, Woosley, and Suzuki.

Corrigan discloses spray drying to form an amorphous forms of phenobarbitone and hydroflumethiazide. According to Corrigan, the amorphous form had increased solubility compared to the crystalline forms. Nonetheless, Corrigan does not cure the deficiencies of the Carr '957 and '129 patents and Woosley. First, Corrigan does not describe or suggest the hydrochloride salt of fexofenadine. Second, there is no motivation in either the Carr '957 and '129 patents, Woosley, or Corrigan to combine the solid fexofenadine with the amorphous solid of Corrigan. Third, for the sake of argument even if there was a motivation to combine the Carr '957 and '129 patents or Woosley

with Corrigan, the result would not be the solid, amorphous fexofenadine hydrochloride of claim 1. Instead, at most, the result would be solid, amorphous fexofenadine. Accordingly, claim 1 and dependent claim 14 are allowed over the Carr '957 and '129 patents, Woosley, and Corrigan, taken separately or in combination.

As amended, independent claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Corrigan, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Corrigan. Specifically, like claim 1, claim 2 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Corrigan.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over the Carr '957 and '129 patents, Woosley, and Corrigan, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Corrigan. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over the Carr '957 and '129 patents, Woosley, and Corrigan.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over the Carr '957 and '129 patents, Woosley, and Corrigan for the same reasons that claims 1 and 2 are allowable over the Carr '957 and '129 patents, Woosley, and Corrigan. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over the Carr '957 and '129 patents, Woosley, and Corrigan.

Nuernberg discloses spray drying drugs to form amorphous drugs that are more soluble than the crystalline drugs. Nonetheless, Nuernberg does not cure the deficiencies of the Carr '957 and '129 patents and Woosley. First, Nuernberg does not describe or suggest the hydrochloride salt of fexofenadine. Second, there is no motivation in either the Carr '957 and '129 patents, Woosley, or Nuernberg to combine the solid fexofenadine with the amorphous solid of Nuernberg. Third, for the sake of argument even if there was a motivation to combine the Carr '957 and '129 patents or Woosley with Nuernberg, the result would not be the solid, amorphous fexofenadine hydrochloride of claim 1. Instead, at most, the result would be solid, amorphous fexofenadine. Accordingly, claim 1 and dependent claim 14 are allowed over the Carr '957 and '129 patents, Woosley, and Nuernberg, taken separately or in combination.

As amended, independent claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Nuernberg, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Nuernberg. Specifically, like claim 1, claim 2 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Nuernberg.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over the Carr '957 and '129 patents, Woosley, and Nuernberg, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Nuernberg. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over the Carr '957 and '129 patents, Woosley, and Nuernberg.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over the Carr '957 and '129 patents, Woosley, and Nuemberg for the same reasons that claims 1 and 2 are allowable over the Carr '957 and '129 patents, Woosley, and Nuernberg. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over the Carr '957 and '129 patents, Woosley, and Nuemberg.

Sata discloses freeze drying and grinding. Nonetheless, Sata does not cure the deficiencies of the Carr '957 and '129 patents and Woosley. First, Sata does not describe or suggest the hydrochloride salt of fexofenadine. Second, there is no motivation in either the Carr '957 and '129 patents, Woosley, or Sata to combine the solid fexofenadine with the freeze dried solid of Sata. Third, for the sake of argument even if there was a motivation to combine the Carr '957 and '129 patents or Woosley with Sata, the result would not be the solid, amorphous fexofenadine hydrochloride of claim 1. Instead, at most, the result would be solid, amorphous fexofenadine. Accordingly, claim 1 and dependent claim 14 are allowed over the Carr '957 and '129 patents, Woosley, and Sata, taken separately or in combination.

As amended, independent claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Sata, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Sata. Specifically, like claim 1, claim 2 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over the Carr '957 and '129 patents, Woosley, and Sata.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over the Carr '957 and '129 patents, Woosley, and Sata, taken separately or in combination, for the same reasons that claim 1 is allowable over the Carr '957 and '129 patents, Woosley, and Sata. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over the Carr '957 and '129 patents, Woosley, and Sata.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over the Carr '957 and '129 patents, Woosley, and Sata for the same reasons that claims 1 and 2 are allowable over the Carr '957 and '129 patents, Woosley, and Sata. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over the Carr '957 and '129 patents, Woosley, and Sata.

Henton discloses a process for obtaining crystalline forms of anhydrous fexofenadine or acid addition salts thereof from a hydrated form by dissolving acid addition salts of hydrated fexofenadine in a solvent and then azeotropically distilling off the solvents to obtain the crystalline fexofenadine. Henton discloses his fexofenadine to be in one or more various crystalline forms (see, e.g., XRD data at Table 1-4) rather than amorphous. Thus, Henton is directed to solving the problem of obtaining crystalline forms of fexofenadine by azeotropic distillation. In his disclosure, Henton does not describe or suggest the amorphous form of the anhydrous fexofenadine acid addition salt. Neither Lieberman, Suzuki, Corrigan, Nuemberg, or Sato, taken separately or in combination cure the deficiencies of Henton to describe the amorphous form of fexofenadine.

As described above, Lieberman states that "[t]heoretical considerations predict that amorphous solids will, in general, be better absorbed than will crystalline ones" but relies instead on micronizing to improve bioavailability. As such, there is no motivation in Lieberman to use an amorphous form because Lieberman uses micronizing to achieve his results. Further, there is no motivation in either Henton or Lieberman to combine the acid addition salt of fexofenadine of Henton with the micronizing of Lieberman. Specifically, Henton is directed to solving problems related to crystalline forms of fexofenadine. Thus, one of skill in the art reading Henton and Lieberman would not have been motivated to combine the solutions provided by Henton, azeotropic distillation to form a crystalline form of fexofenadine, with the micronizing of Lieberman. For the sake of argument, even if there was a motivation to combine Henton with Lieberman, the result would not be the solid, amorphous fexofenadine hydrochloride of claim 1. Instead, at most, the result would be the micronized, crystalline acid addition salt of fexofenadine. Accordingly, claim 1 and dependent claim 14 are allowable over Henton and Lieberman, taken separately or in combination.

As amended, independent claim 2 is allowable over Henton and Lieberman, taken separately or in combination, for the same reasons that claim 1 is allowable over the Henton and Lieberman. Specifically, like claim 1, claim 2 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over Henton and Lieberman.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over Henton and Lieberman, taken separately or in combination, for the same reasons that claim 1 is allowable over Henton and Lieberman. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over Henton and Lieberman.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over Henton and Lieberman for the same reasons that claims 1 and 2 are allowable over Henton and Lieberman. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over Henton and Lieberman.

Suzuki discloses particle size reduction by freeze drying using a water-potassium chloride system and a water-sodium chloride system. See page 1214. Suzuki further discloses that some antibiotics and enzymes are frequently freeze-dried as amorphous form because the amorphous form is superior to the crystalline form with respect to solubility. However, Suzuki denigrates the use of the amorphous form by stating: "their [amorphous form] hygroscopisity [sic] and reduced stability may be disadvantageous in practical use." See page 1218. Thus, one of skill in the art reading Suzuki would not have been motivated to use the amorphous form. In fact, because of the denigration of the amorphous form, one of skill in the art would have been taught away from using the amorphous form. Thus, contrary to the Office Action, one of skill in the art reading Henton and Suzuki would not have been motivated to use the crystalline, acid addition salt of fexofenadine of Henton with the amorphous form of Suzuki. Accordingly claim 1 and dependent claim 14 are allowable over Henton and Suzuki, taken separately or in combination.

As amended, independent claim 2 is allowable over Henton and Lieberman, taken separately or in combination, for the same reasons that claim 1 is allowable over the Henton and Lieberman. Specifically, like claim 1, claim 2 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over Henton and Lieberman.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over Henton and Lieberman, taken separately or in combination, for the same reasons that claim 1 is allowable over Henton and Lieberman. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over Henton and Lieberman.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over Henton and Lieberman for the same reasons that claims 1 and 2 are allowable over Henton and Lieberman. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over Henton and Lieberman.

Corrigan discloses spray drying to form an amorphous forms of phenobarbitone and hydroflumethiazide. According to Corrigan, the amorphous form had increased solubility compared to the crystalline forms. Nonetheless, Corrigan does not cure the deficiencies of Henton and provide a motivation to modify the crystalline acid addition salt of fexofenadine of Henton with the amorphous solid of Corrigan. To modify Henton in that manner would be to ignore the clear teaching of Henton with regard to crystalline fexofenadine. Accordingly, claim 1 and dependent claim 14 are allowed over Henton and Corrigan, taken separately or in combination.

As amended, independent claim 2 is allowable over Henton and Corrigan, taken separately or in combination, for the same reasons that claim 1 is allowable over the Henton and Corrigan. Specifically, like claim 1, claim 2 recites the solid, amorphous

form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over Henton and Corrigan.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over Henton and Corrigan, taken separately or in combination, for the same reasons that claim 1 is allowable over Henton and Corrigan. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over Henton and Corrigan.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over Henton and Corrigan for the same reasons that claims 1 and 2 are allowable over Henton and Corrigan. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over Henton and Corrigan.

Nuernberg discloses spray drying drugs to form amorphous drugs that are more soluble than the crystalline drugs. Nonetheless, Nuernberg does not cure the deficiencies of Henton and provide a motivation to modify the teaching of Henton, namely, azeotropic distillation to form crystalline fexofenadine, with the spray drying of Nuernberg. Accordingly, claim 1 and dependent claim 14 are allowed over Henton and Nuernberg, taken separately or in combination.

As amended, independent claim 2 is allowable over Henton and Nuernberg, taken separately or in combination, for the same reasons that claim 1 is allowable over the Henton and Nuernberg. Specifically, like claim 1, claim 2 recites the solid, amorphous

form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over Henton and Nuernberg.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over Henton and Nuernberg, taken separately or in combination, for the same reasons that claim 1 is allowable over Henton and Nuernberg. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over Henton and Nuernberg.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over Henton and Nuernberg for the same reasons that claims 1 and 2 are allowable over Henton and Nuernberg. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over Henton and Nuernberg.

Sata discloses freeze drying and grinding. Nonetheless, Sata does not cure the deficiencies of Henton and provide a motivation to modify the teaching of Henton, namely, azeotropic distillation to form crystalline fexofenadine, with the freeze drying and grinding of Sata. Accordingly, claim 1 and dependent claim 14 are allowed over Henton and Sata, taken separately or in combination.

As amended, independent claim 2 is allowable over Henton and Sata, taken separately or in combination, for the same reasons that claim 1 is allowable over the Henton and Sata. Specifically, like claim 1, claim 2 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 2 is allowable over Henton and Sata.

As amended, independent claim 3 is directed to a process of making a solid, amorphous form of fexofenadine hydrochloride. As such, independent claim 3 is allowable over Henton and Sata, taken separately or in combination, for the same reasons that claim 1 is allowable over Henton and Sata. Specifically, like claim 1, claim 3 recites the solid, amorphous form of fexofenadine hydrochloride. Accordingly, claim 3 and dependent claims 4-13 are allowable over Henton and Sata.

New independent claim 15 is directed to a method of treating a condition for which fexofenadine hydrochloride is indicated. The method includes providing a dosage form that includes a solid, amorphous fexofenadine hydrochloride. Thus, like claim 1, Claim 15 recites a solid, amorphous fexofenadine hydrochloride and therefore is allowable over Henton and Sata for the same reasons that claims 1 and 2 are allowable over Henton and Sata. Accordingly, claim 15 and dependent claims 16 and 17 are allowable over Henton and Sata.

IV. Provisional rejection under 35 U.S.C. 102(e), (f) and (g) as being anticipated by US2002/01776608 and WO02/066429.

U.S. patent application 2002/01776608 has a filing date of April 08, 2002 and a provisional date of April 09, 2001 and discloses an amorphous product, which is produced by employing a drying step. WO02/066429 has a filing date of January 12, 2002, with a priority date of February 23, 2001, and discloses an amorphous product of fexofenadine and a process for making it.

Applicants respectfully submit that the inventors can swear behind US2002/01776608 and WO02/066429. Because these rejections are provisional, declarations swearing behind these references will be provided when the other rejections of the claims are overcome.

Conclusion

For the reasons stated above, the Examiner is urged to allow claims 1-17. Applicant requests a three month extension of time to respond to the Office Action dated June 9, 2003. Authorization is hereby given to charge the three month extension of time and any other fees deemed to be due in connection with this Response to Office Action to Deposit Account No. 50-0912.

Respectfully submitted,

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